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EXAMINER

FLEURANTIN, J

ART UNIT

PAPER NUMBER

2172

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/025,279

Applicant(s)
Robert H. Shelton

Examiner
Jean Bolte Fleurantin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Appeal Brief 06/13/01
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. Claims 1-81 are remained for examination.
2. Applicant submitted the Appeal Brief on 06/08/01. Examiner has carefully review the appellant's argument. An appeal panel met to determine the patentability of the present invention over the prior art Evans. Examiner did not clearly cite the passage in Evans that teach the claimed data processing means, specially the claimed when said request fails to comply with said conditions, for denying access to said data. Since the Examiner needs to redirect the applicant to another citation and claims 3, 44 receive a new ground of rejection, Examiner withdraws the finality of the final action mailed 11/21/2000.

Response to Arguments

3. As per claims 1 and 42, Applicant argues that the admitted prior art does not teach or fairly suggest:

In response to applicant's argument on pages 5, 19-21, and 23 that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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Applicant discussed that “a claimed is not limited to the details of the preferred embodiment set forth in the specification, claims are interpreted in light of the specification”. However, the claimed conditions required for accessing medical data, 1) has its clear meaning, and 2) does not provide the meaning of “an initial blanket approval, a prior approval for a limited number of people, or express approval by the patient for access by a party newly requesting access”.

Applicant stated on page 16, that Evans does not specifically disclose a “data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data and, when said request fails to comply with said conditions, for denying access to said data”. However, Evans shows the step of the point of care system issues a request for patient data with reference to figure 15a, the patient locator receives the request from the point of care system and attempts to find the patient id for the record having the requested patient data as determined, if no patient id is found the patient locator reports an error at this point the patient data repository may recover from the error by either restarting the process or by ending the process; which is readable as data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data) (see figure 15, col. 9, lines 39-48). Thus, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Evans with the step of data

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processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data. This modification would allow the teachings of Evans to provide efficiently cost effective to move data instead of physical records and health care providers, and eliminates the mishandling loss, destruction of patient data typically associated with maintenance of physical data records (see col. 14, lines 30-41).

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2, 4-43, and 45-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (U.S. Pat. No. 5,924,074).

As per claims 1 and 42, Evans substantially teaches a medical data base supervisory control system as claimed comprises at least one database including medical data individually relating to each of a plurality of patients (thus, the system likewise permits instant sophisticated analysis of patient data to identify relationships among the data considered, which is readable as medical data individually relating to each of a plurality of patients) (see, abstract, lines 1-17),

(b) means including interconnected computers for requesting and accessing said medical data (abstract, lines 5-12) and (see, figure 24, element 404),

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(c) means for identifying medical data for each of said patients with condition required for accessing said medical data (thus, authorized health care providers can access a record while other providers use the same record, which is readable as identifying medical data for each of said patients with condition required for accessing said medical data) (see, col. 2, lines 53-64).

But, Evans does not explicitly indicate the step of the data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data. However, Evans implicitly shows the step of the point of care system issues a request for patient data with reference to figure 15a, the patient locator receives the request from the point of care system and attempts to find the patient id for the record having the requested patient data as determined, if no patient id is found the patient locator reports an error at this point the patient data repository may recover from the error by either restarting the process or by ending the process; which is readable as data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data) (see figure 15, col. 9, lines 39-48). Also, in column 3, lines 9 through 24 Evans teaches wherein the patient record includes identifier and at least one data structure including the patient identifier and the data. Thus, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Evans with the step of data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and,

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when said request fails to comply with said conditions, for denying access to said data. This modification would allow the teachings of Evans to improve the accuracy and the reliability of the standing order database search system and method for internet and internet application, and provide instant access to a patient's electronic medical record by authorized health care providers from any geographical location (see col. 14, lines 65-67).

As per claims 2, 5, 43, and 46 Evans substantially teaches a system as claimed further includes means for authenticating the identity of the requesting party (thus, the system provides several levels of security for access to patient data, which is readable as the identity of the requesting party) (see col. 15, lines 21-29).

As per claims 4 and 45, Evans substantially teaches a method as claimed further includes the step of tentatively identifying records fulfilling the criteria specified in said request for medical (thus, the health care provider can track referrals by entering the identity of persons who referred this patient to their care, which is readable as tentatively identifying records fulfilling the criteria specified in said request for medical) (see, col. 6, lines 7-9).

As per claims 6-7, and 47-48 Evans substantially teaches a system as claimed, wherein said means for requesting said medical data includes means for indicating what part of said records is desired (see, figure 15A).

As per claims 8-9 and 49-50, Evans substantially teaches a system as claimed, wherein said means for identifying records fulfilling such request further include data symbolic of medical symptoms or reason for patient visit (thus, the health care provider can track referrals by entering

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the identity of persons who referred this patient to their care, which is readable as wherein said means for identifying records fulfilling such request further include data symbolic of medical symptoms) (see, figure 15A, elements 252, 254, cols. 6 and 9, lines 7-9, and 41-50).

As per claims 10-11 and 51-52, Evans substantially teaches a system as claimed, wherein said means for identifying records fulfilling such request further include data symbolic of the attributes, levels or findings indicated within said diagnostic tests (thus, the system returns the provider to the patient chart window, which is readable as identifying records fulfilling) (see, figure 7, col. 7, lines 10-28).

As per claims 12-13 and 53-54, Evans substantially teaches a system as claimed, wherein said means for identifying records fulfilling such request further include data symbolic of modes of treatment or medical services rendered (thus, to consult regarding courses of action to obtain a diagnosis, which is readable as include data symbolic of modes of treatment or medical services rendered) (see, col. 7, lines 54-64).

As per claims 14-15 and 55-56, Evans substantially teaches a system wherein said means used for identifying records fulfilling such request further include data symbolic of attending physician identity (thus, permits health care providers such as physicians to electronically annotate patient data, which is readable as identifying records fulfilling such request further include data symbolic of attending physician identity) (see, col. 2, lines 50-54).

As per claims 16, 30 and 57, Evans substantially teaches as claimed, wherein said means for requesting and accessing said medical data includes means for indicating a "standing order"

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that will automatically initiate an attempt to retrieve certain pre-determined types of medical data under specific pre-specified circumstances (see, col. 2, lines 21-31).

As per claims 17, 58 and 63, Evans substantially teaches a system as claimed, wherein said conditions required for accessing said medical data includes an indication of the names of each of the parties who's permission must be obtained prior to the release of the such medical data (thus, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data, which is readable as for accessing said medical data includes an indication of the names of each of the parties who's permission must be obtained prior to the release of the such medical data) (see, col. 3, lines 6-8).

As per claims 18-19, 59-61 and 78, Evans substantially teaches a system as claimed, wherein said conditions required for accessing said medical data further includes an indication of the charge that will be assessed by the holder of such medical data for the part, or in the form, specified by the requesting party (see, cols. 6 and 7, lines 54-67, and 1-5).

As per claims 20, 22, 34 and 75, Evans substantially teaches a system as claimed, wherein said at least one data base includes a firewall limiting access to searching such data base solely to those parties who are authorized to do so (thus, system administrator may have global password access, which is readable as said at least one data base includes a firewall limiting access to searching) (see, col. 15, lines 24-29).

As per claims 21, 31, 62 and 72, Evans substantially teaches a system as claimed, wherein said means for identifying medical data fulfilling the criteria specified in a request include a

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means for producing an indicia of the degree to which data listed in such data index match the criteria specified in such request (thus, group data associated with a patient within the data archive for rapid retrieval in a manner similar to files within a directory in an operating system, which is readable as identifying medical data fulfilling the criteria specified in a request include a means for producing an indicia of the degree to which data listed in such data index match the criteria specified in such request) (see, col. 9, lines 28-37).

As per claims 23 and 67, Evans substantially teaches a system as claimed, wherein said at least one data base includes a billing means for access to said medical data (thus these files may also include the patient's billing payment and scheduling records, which is readable as wherein said at least one data base includes a billing means for access to said medical data) (see, col. 1, lines 25-30).

As per claims 24-25, 64 and 66, Evans substantially teaches a system as claimed, wherein said means to grant permission includes data symbolic of the identity of such party and data symbolic of the preferred means for contacting such party to request access to and release of said patient's medical data (see, abstract, lines 5-17).

As per claims 26, 43 and 45-46, Evans substantially teaches a system as claimed, further includes means for identifying the party requesting access to such medical data (see, figures 17A and 17B, col. 10, lines 42).

As per claims 27-29, 68-69 and 73, Evans substantially teaches a method as claimed, further includes means for producing an indicia of the required approvals for the release of such

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medical data that have not been secured, or that have been specifically declined (see, col. 2, lines 53-60).

As per claims 32-33 and 40, Evans substantially teaches a system as claimed, further includes means for billing said requesting party for the charge related to access to the medical data (thus these files may also include the patient's billing payment and scheduling which is readable as records means for billing said requesting party for the charge related to access to the medical data) (see col. 1, lines 25-30).

As per claims 35-36 and 71, Evans substantially teaches a system as claimed, further includes means for producing an indicia that the requested medical data have been received in an online memory cache means and are being held there for download by the requesting party (see, cols. 9 and 10, lines 61-67, and 1-17).

As per claims 37, 39, 47 and 80-81, Evans substantially teaches a method as claimed, further includes the step of creating a security log and retaining an audit trail with regard to all of the communications between the parties (see, col. 3, lines 25-30).

As per claims 38, 74 and 79, Evans substantially teaches a system as claimed, further includes means for informing the requesting party when medical data is in a non-digital form and the mode of such delivery (see, col. 1, lines 53-64).

As per claim 41, Evans discloses a system as claimed, further comprises means for allowing parties to advertise in the public portions of said system (see, figure 22).

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As per claim 65 and 70, Evan substantially teaches a method as claimed, wherein said step of providing for a party to grant permission includes data symbolic of the identity of such party and data symbolic of the preferred means for contacting such party to request access to and to the release of said patient's medical data (see, col. 2, lines 53-60).

As per claims 76 and 77, Evans substantially teaches a method as claimed, further includes the step of permitting a properly credentialed requesting party to enter through the firewall and download said medical data from the memory cache (thus, if the data in the cache is not ready for transfer the process ends and the data manager queues the request for the next transfer of data to the data archive, which is readable as permitting a properly credentialed requesting party to enter through the firewall and download said medical data from the memory cache) (see, col. 10, lines 10-17).

6. Claims 3 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (U.S. Pat. No. 5,924,074) in view of Anderson, R.J. (A security policy model for clinical information system; 6-8 May, 1996) ("Anderson").

As per claims 3 and 44, Evans teaches all the subject matter of the claimed invention with the exception of an exact including means to prevent access to formation concerning medical records by any party without the prior authorization of the patient about whom such records pertain. However, Anderson teaches the step of the patient's consent must be sought for other person such as the clinician's colleagues to be added to the access control list and must be notified of every addition; which is readable as including means to prevent access to formation

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concerning medical records by any party without the prior authorization of the patient about whom such records pertain (see page 35, cols. 1 and 2, lines 46-9, and 1-4). Also, in page 31, column 1, lines 42 through 44, Anderson teaches the step if researchers want access to records which cannot effectively be made anonymous, then every effort must be made to inform the patient and gain his consent. Thus, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Evans with the teachings of Anderson with the step of to prevent access to formation concerning medical records by any party without the prior authorization of the patient about whom such records pertain. Thus, this modification would allow the teachings of Evans and Anderson to improve the accuracy and the reliability of the standing order database search system and method for internet and internet application, and provide ensure that any lack of consent is propagated and enforced (see page 41, col. 2, lines 49-50).

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson, R.J. (A security policy model for clinical information system; 6-8 May, 1996)

Conclusion

8. Any inquiry concerning this communication from examiner should be directed to Jean Bolte Fleurantin at (703) 308-6718. The examiner can normally be reached on Monday to Friday from 7:30 A.M. to 6.00 P.M.

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If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Mrs. KIM VU can be reached at (703) 305-8449. The FAX phone number is (703) 305-9731.

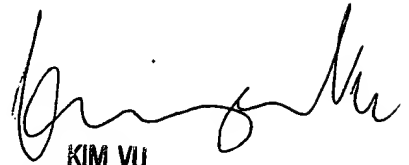
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone is (703) 305-9600.



Jean Bolte Fleurantin

August 27, 2001

JBf/



KIM VU
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